

5 510 (k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Date Prepared: January 9, 2007

MAR 09 2007

510(k) number: K070275

Applicant Information:

Rubicor Medical, Inc.
600 Chesapeake Dr.
Redwood City, CA 94063

Contact Person: Chris Daniel
Phone Number: (650) 556-1070
Fax Number: (650) 556-1821

Device Information:

Classification: Class II
Common Name: Electrosurgical Electrode
Trade Name: Not yet determined
Classification Name: Electrosurgical Device and accessories (21 CFR 878.4400)

Equivalent Device:

The subject device and accessory are substantially equivalent in intended use and/or method of operation to the Rubicor EnCapsule™ Breast Biopsy Device (K052506), SenoRx Shape Select Scalpel (K012799), Wallach LOOP Electrodes (K020711), and Megadyne Electrosurgical Electrode (K973346).

Intended Use:

The Rubicor Flexible Loop Electrosurgical Electrode is intended for diagnostic sampling of breast tissue during breast biopsy procedures. It is to be used for diagnostic purposes only and is not intended for therapeutic uses. It is also intended to cut soft tissue.

The Rubicor Flexible Loop Electrosurgical Electrode is indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities. It is designed to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality.

The extent of histologic abnormality cannot be reliably determined from its mammographic appearance. Therefore, the extent of removal of the imaged evidence of an abnormality does not predict the extent of removal of a histologic abnormality (e.g., malignancy). When the sampled abnormality is not histologically benign, it is essential

that the tissue margins be examined for completeness of removal using standard surgical procedures.

Test Results:

Performance

Results of in-vitro testing demonstrate that the Flexible Loop Electrosurgical Electrode is safe and effective for its intended function.

Summary:

Based on the intended use, product, and performance information provided in this notification, the subject device has been shown to be substantially equivalent to the currently marketed predicate device(s).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Rubicor Medical, Inc.
% Underwriters Laboratories, Inc.
Mr. Morten Simon Christensen
Staff Engineer & FDA Office Coordinator
Medical Device Services
455 East Trimble Road
San Jose, California 95131-1230

MAR 09 2007

Re: K070275

Trade/Device Name: Flexible Loop Electrosurgical Electrode
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: February 22, 2007
Received: February 23, 2007

Dear Mr. Christensen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

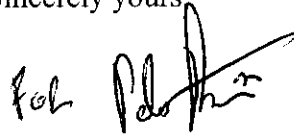
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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours

A handwritten signature in black ink, appearing to read 'Mark N. Melkerson', with a stylized flourish at the end.

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4 Indication for Use Statement

510(k) Number (if known): K070275Device Name: Flexible Loop Electrosurgical Electrode**Indications for Use:**

The Rubicor Flexible Loop Electrosurgical Electrode is intended for diagnostic sampling of breast tissue during breast biopsy procedures. It is to be used for diagnostic purposes only and is not intended for therapeutic uses. It is also intended to be used to cut soft tissue.

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of General Restorative,
and Neurological Devices

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